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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
10/579,850	05/17/2006	Deborah Addison	101713-5041	8913

28977 7590 06/22/2009
MORGAN, LEWIS & BOCKIUS LLP
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EXAMINER

ROBINSON, JAMES MARSHALL

ART UNIT	PAPER NUMBER
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3772

MAIL DATE	DELIVERY MODE
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06/22/2009

PAPER

Please find below and/or attached an Office communication concerning this application or proceeding.

The time period for reply, if any, is set in the attached communication.

Office Action Summary	Application No. 10/579,850	Applicant(s) ADDISON ET AL.	
	Examiner James M. Robinson	Art Unit 3772	

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

- 1) ☐ Responsive to communication(s) filed on 23 April 2009.
- 2a) ☐ This action is **FINAL**. 2b) ☒ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

- 4) ☒ Claim(s) 1-5,7-13,20 and 21 is/are pending in the application.
- 4a) Of the above claim(s) _____ is/are withdrawn from consideration.
- 5) ☐ Claim(s) _____ is/are allowed.
- 6) ☒ Claim(s) 1-5,7-13,20 and 21 is/are rejected.
- 7) ☐ Claim(s) _____ is/are objected to.
- 8) ☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

- 9) ☐ The specification is objected to by the Examiner.
- 10) ☐ The drawing(s) filed on _____ is/are: a) ☐ accepted or b) ☐ objected to by the Examiner.
Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).
Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).
- 11) ☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

- 12) ☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
- a) ☐ All b) ☐ Some * c) ☐ None of:
1. ☐ Certified copies of the priority documents have been received.
 2. ☐ Certified copies of the priority documents have been received in Application No. _____.
 3. ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

- | | |
|--|---|
| 1) <input checked="" type="checkbox"/> Notice of References Cited (PTO-892) | 4) <input type="checkbox"/> Interview Summary (PTO-413) |
| 2) <input type="checkbox"/> Notice of Draftsperson's Patent Drawing Review (PTO-948) | Paper No(s)/Mail Date. _____ |
| 3) <input type="checkbox"/> Information Disclosure Statement(s) (PTO/SB/08) | 5) <input type="checkbox"/> Notice of Informal Patent Application |
| Paper No(s)/Mail Date _____ | 6) <input type="checkbox"/> Other: _____ |

DETAILED ACTION

This action is in response to amendments/arguments filed 4/23/2009. Currently claims 1-5, 7-13, 20 and 21 are pending and claims 1, 2 and 7 have been amended. Claims 20 and 21 have been added.

Response to Arguments

1. Applicant's arguments filed 4/23/2009 have been fully considered but they are not persuasive. With respect to applicant's position that Canada et al. does not disclose a dyestuff to photostabilize the silver salt, examiner respectfully disagrees. As disclosed by applicant, on page 11 lines 6-20, applicant discloses the dyestuffs can stabilize the silver salts against photochemical decomposition by absorbing light near the surface of the material. The dyestuffs also trap photochemically generated free radicals that could otherwise react with the silver. In this way the dyestuffs can act as a photochemical desensitizer. Thus, in the manner as disclosed by applicant, the dyestuff taught by Canada et al. in column 7, lines 53-61 function as, and comprises a silver salt photostabilizer. Applicant's arguments with respect to claims 8-10 have been considered but are moot in view of the new ground(s) of rejection.

Specification

2. The specification is objected to as failing to provide proper antecedent basis for the claimed subject matter. See 37 CFR 1.75(d)(1) and MPEP § 608.01(o). Correction of the following is required: The dyestuff comprising a silver salt photostabilizer does not provide proper antecedent basis for the claimed subject matter.

Claim Rejections - 35 USC § 112

3. The following is a quotation of the first paragraph of 35 U.S.C. 112:

The specification shall contain a written description of the invention, and of the manner and process of making and using it, in such full, clear, concise, and exact terms as to enable any person skilled in the art to which it pertains, or with which it is most nearly connected, to make and use the same and shall set forth the best mode contemplated by the inventor of carrying out his invention.

4. Claim 1 is rejected under 35 U.S.C. 112, first paragraph, as failing to comply with the written description requirement. The claim(s) contains subject matter which was not described in the specification in such a way as to reasonably convey to one skilled in the relevant art that the inventor(s), at the time the application was filed, had possession of the claimed invention. The amended recitation -- wherein the dyestuff comprises a silver salt photostabilizer -- is treated as new matter. The disclosure does not have support for a dyestuff comprising a silver salt photostabilizer. The original disclosure teaches on page 11 lines 6-20 -- the dyestuffs can stabilize the silver salts against photochemical decomposition by absorbing light near the surface of the material. The dyestuffs also trap photochemically generated free radicals that could otherwise react with the silver. In this way the dyestuffs can act as a photochemical desensitizer --. It is clear from applicant's disclosure that the dyestuff is intended to function as silver salt photostabilizer. However, support does not exist for the presence of any additional additives to the dyestuff of silver salt photostabilizers.

5. The following is a quotation of the second paragraph of 35 U.S.C. 112:

The specification shall conclude with one or more claims particularly pointing out and distinctly claiming the subject matter which the applicant regards as his invention.

6. Claim 20 is rejected under 35 U.S.C. 112, second paragraph, as being indefinite for failing to particularly point out and distinctly claim the subject matter which applicant regards as the invention. The limitation -- a dyestuff in sufficient amount to stabilize the silver salt -- renders the claim indefinite. A "sufficient amount" is vague and indefinite. The metes and bounds of the claim are not clearly defined. Appropriate correction is requested.

Claim Rejections - 35 USC § 102

7. The following is a quotation of the appropriate paragraphs of 35 U.S.C. 102 that form the basis for the rejections under this section made in this Office action:

A person shall be entitled to a patent unless –

(e) the invention was described in (1) an application for patent, published under section 122(b), by another filed in the United States before the invention by the applicant for patent or (2) a patent granted on an application for patent by another filed in the United States before the invention by the applicant for patent, except that an international application filed under the treaty defined in section 351(a) shall have the effects for purposes of this subsection of an application filed in the United States only if the international application designated the United States and was published under Article 21(2) of such treaty in the English language.

8. Claims 1- 5, 7, 11, 13, 20 and 21 are rejected under 35 U.S.C. 102(e) as being anticipated by Canada et al. (US 7118761).

Regarding claims 1, 20 and 21 Canada discloses a wound dressing material (col. 1, lines 7-8) comprising a polymeric substrate (col. 6, lines 15-27), a silver salt (col. 8, lines 21-42) which is a complex of Ag⁺ and an anionic polymer, and a dyestuff (col. 7, lines 53-61) which is, and therefore comprises a silver salt photostabilizer. Regarding the limitation of claim 20, "dyestuff in sufficient amount to stabilize the silver salt," the limitation has been treated as an intended use recitation. It has been held that a

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recitation with respect to the manner in which a claimed apparatus is intended to be employed does not differentiate the claimed apparatus from a prior art apparatus satisfying the claimed structural limitations. Ex parte Masham, 2 USPQ2d 1647 (1987). Since the limitation has not been positively claimed, the dyestuff of the Lilienfeld patent is capable of performing the recited function.

Regarding claims 2-5, Canada discloses a wound dressing material wherein the substrate comprises a solid biabsorbable material such as oxidized cellulose (col. 6, lines 25-26) in woven form (col. 5, lines 27-29).

Regarding claim 7, Canada discloses a wound dressing material wherein the silver salt comprises from about 0.01 wt. % to about 5 wt. % of silver, based on the dry weight of the composition (col. 8, lines 43-55).

Regarding claim 11, Canada discloses a wound dressing material wherein the polymeric substrate consists essentially of a mixture of an oxidized cellulose with a collagen, a chitosan, or both a collagen and a chitosan (col. 4 lines 60 - col. 5, line 1).

Regarding claims 13, there is no positive claimed structure but rather a property met by a test is claimed. The properties of the wound dressing material disclosed in Lilienfeld are the same as those claimed by applicant; therefore Lilienfeld's material would be capable of, if subjected to the DPPH test, exhibiting essentially an antioxidant activity of at least about 15%. Therefore, the limitations of the claim are met.

Claim Rejections - 35 USC § 103

1. The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

(a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negated by the manner in which the invention was made.

Claims 8-10 are rejected under 35 U.S.C. 103(a) as being unpatentable over Canada et al. (US 7118761) in view of Camden (US 6136835). Canada substantially discloses the invention as claimed; see rejections to claims 1- 5 and 7 above, including wherein the dyestuff comprises an antioxidant dyestuff (col. 7, lines 53-61). However, Canada is silent to the exact dyestuff selected.

Camden discloses a transdermal patch or dressing such as a bandage (col 16 ln 17-26) impregnated with an active ingredient to treat viral infection (col 1 ln 13-15) which includes suramin and analogues thereof (col. 13, lines 16-17) which is a known analog of trypan blue.

It would have been obvious to one having ordinary skill in the art at the time of the invention to provide the wound dressing material of Canada with a dyestuff that is of the antioxidant type such as the trypan blue analog suramin in view of the teachings of Camden in order to utilize an antioxidant type dye that is biocompatible.

Regarding claim 10, Canada fails to explicitly disclose the dyestuff is present in an amount of from about 0.2 to about 2wt.% based on the dry weight of the material.

To provide the wound dressing material of Canada with a composition comprising from about 0.2 to about 2wt.% based on the dry weight of the material of

dyestuff, based on the dry weight of the composition, it would have been obvious to one of ordinary skill in the art at the time of the invention, in view of the teachings of Camden, in order to optimize the anti-microbial effect of the dressing material. Further, it would be obvious to one of ordinary skill in the art to have chosen an optimal concentration by weight of dyestuff, within the claimed range, since it has been held that discovering an optimum value of a result effective variable involves only routine skill in the art. In re Boesch, 617 F.2d 272, 205 USPQ 215 (CCPA 1980).

2. Claim 12 is rejected under 35 U.S.C. 103(a) as being unpatentable over Canada et al. (US 7118761) in view of Hirsch (1962900).

Regarding claims 12, Canada fails to disclose the use of packaging.

However, Hirsch discloses a wound dressing material wherein the material is packaged in a sterile container (lines 5-11). Further, is well known and conventional in the art of wound dressings to package wound dressing and keep it sterile prior to use and ensure that the dressing will prevent contamination of the wound at the site of bandage application.

It would have been obvious to one of ordinary skill in the art at the time of the invention to package the wound dressing of Canada with the microorganism impermeable container of Hirsch in order to maintain dressing sterility.

Conclusion

Any inquiry concerning this communication or earlier communications from the examiner should be directed to James M. Robinson whose telephone number is (571) 270-3867. The examiner can normally be reached on Mon-Fri 9AM-5PM.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Patricia Bianco can be reached on (571)272-4940. The fax phone number for the organization where this application or proceeding is assigned is 571-273-8300.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see <http://pair-direct.uspto.gov>. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free). If you would like assistance from a USPTO Customer Service Representative or access to the automated information system, call 800-786-9199 (IN USA OR CANADA) or 571-272-1000.

/James M. Robinson/

/Patricia Bianco/
Supervisory Patent Examiner, Art Unit 3772